## REMARKS

Claims 1-15 are pending in the present application. Claim 1 has been amended, and claims 3 and 4 have been canceled without prejudice to or disclaimer of the underlying subject matter. Support for the amended claims can be found throughout the specification and claims as originally filed, for example on page 4, lines 14-26. No new matter enters by way of this amendment. Upon entry of the foregoing amendment, claims 1-2 and 5-15 will be pending.

Reexamination of the application and reconsideration of the rejections and objections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

### I. Introductory Comments

Prior to addressing the rejections of record, a brief description of the disclosure is provided for the convenience of the Examiner. The disclosure provides a wound treatment device comprising a water-impermeable envelope having at least one aperture. The envelope contains a therapeutic agent, and the at least one aperture is blocked by a degradable material that breaks down in the presence of one or more components of wound fluid, thereby permitting the therapeutic agent to contact the wound fluid. The envelope is a "small package or enclosure that can be inserted onto or into a wound," such that "[t]he device can be used in conjunction with a wide range of existing wound dressings, and is sufficiently small that it will not interfere with the absorbency of such dressings." *Specification* at page 3 lines 14-26. As the specification discusses, the "[t]ypical envelope configuration is a sachet formed by bonding together two sheets of film material (or one sheet folded over) around a periphery." *Specification* at page 4, lines 9-11.

### II. Claim Rejections under 35 U.S.C. § 102(e)

Claims 1-3 and 5-15 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Kirkwood et al., U.S. Application Publication No. 2004/0241214 (hereinafter "Kirkwood et al."), which, as the Final Action notes, has common inventors with the present application. *Office Action* at pages 3-4. Applicants respectfully traverse for at least the following reasons.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 1, as amended, is directed to a wound treatment device comprising a water-impermeable envelope having at least one aperture, where the envelope contains a therapeutic agent, and where the at least one aperture in the envelope is blocked by a degradable material that breaks down in the presence of one or more components of wound fluid thereby permitting the therapeutic agent to contact the wound fluid, and where the envelope has only one aperture and where the total area of the aperture in the envelope is from about 0.01 to about 1 $cm^2$. Claim 1 has been amended to include the feature of dependent claim 4, which the Examiner acknowledges is not disclosed in the Kirkwood et al. disclosure.

Accordingly, Kirkwood et al. does not disclose all of the features of independent claim 1 as amended. Since the cited reference does not anticipate claim 1, neither does it anticipate dependent claims 2 and 5-15. As such, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(e).

## III. Claim Rejections under 35 U.S.C. § 103

A. Rejection of Claim 4

Claim 4 has been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kirkwood et al. (U.S. Patent Application No. 2004/0241214). *Office Action* at page 5. Applicants respectfully traverse for at least the following reasons.

As claim 4 has been canceled without prejudice to or disclaimer of the underlying subject matter, this rejection is moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 4 under 35 U.S.C. § 103(a).

B. Rejection of Claims 1-15

Claims 1-15 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Arnold (U.S. Patent No. 5,759,570) in view of Burton (U.S. Patent No. 6,903,243). *Office Action* at page 5. Claims 3 and 4 have been canceled without prejudice to or disclaimer of the underlying subject matter, and therefore Applicants respond to the rejection with respect to claims 1-2 and 5-15. Applicants respectfully traverse for at least the following reasons.

Claim 1 has been amended to recite a wound treatment device comprising a water-impermeable envelope having at least one aperture, where the envelope contains a therapeutic agent, and where the at least one aperture in the envelope is blocked by a degradable material that breaks down in the presence of one or more components of wound fluid thereby permitting the therapeutic agent to contact the wound fluid, and where the envelope has only one aperture and where the total area of the aperture in the envelope is from about 0.01 to about 1 $cm^2$.

The Final Action alleges that "it would have been obvious to modify the Arnold/Burton device to have apertures of size about 0.01 to 1 $cm^2$ because it fails to patentably distinguish the device." *Final Action*, at page 7. The Final Action also alleges that "Applicant fails to disclose that the claimed size aperture provides a specific advantage or solves a stated problem, [and] therefore the Burton aperture size of less than 70% of the thickness [of the] absorbent layers would function equally as well." *Id.*, at pages 6-7. The Final Action further alleges that "it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Arnold device with the apertured layer over the degradable layer, as taught by Burton, in order to force the exudates towards the absorbent later and not allow a build up of exudates that may cause the wound dressing to fall off the skin." *Id.* at page 6.

Initially, the Final Action does not show that the combined references disclose or suggest all of the features of the currently claimed invention. For example, the Final Action does not show that the combined references disclose or suggest device having the recited envelope having at least one aperture in the aperture that is blocked by a degradable material. The Action acknowledges that "Arnold fails to disclose an aperture, of an area about 0.01 to 1 $cm^2$, in the envelope that is blocked by a biodegradable material." *Id.*, at page 6. The Final Action further states that "Burton teaches a wound dressing (10) with an aperture in the wound facing layer." *Id.* However, nothing that the Final Action points to indicates that Burton discloses an envelope containing a therapeutic agent and having an aperture blocked by a degradable material. As such, the Final Action has not shown that the combination of references discloses all of the recited features.

Furthermore, the Final Action does not provide any reasoning why a skilled artisan would modify the wound dressing of Arnold as suggested by the Final Action. *See,* MPEP § 2142. As the Arnold reference states, the disclosed wound dressing has "a maximum pore size in the range of from 0.001 um to 0.5 um." Col. 1, lines 61-63. Arnold goes on to

indicate that the wound dressing "provides an improved wound healing environment at the wound site. It achieves this by retaining at the wound site those wound healing factors such as cytokines (e.g. TGKB, FGFB, EGF, PDGF, IL-1 and others), glycosaminoglycans and proteins that have molecular weights too high to enable them to pass through the molecular filtration membrane." Col. 2, line 61 through Col. 3, line 1. The Arnold reference further teaches that "[a]t the same time, excess water and low molecular weight molecules from the wound exudate are swiftly removed through the molecular filtration membrane into the absorbent layer." Col. 3, lines 4-7. A skilled artisan would not have modified the Arnold dressing in the manner alleged by the Final Action as the proposed modification would have rendered the Arnold device unsatisfactory for its disclosed purpose. *See, e.g.*, MPEP § 2143.01V. Modification of the Arnold dressing to include apertures of the recited size would not provide the "wound healing environment at the wound site" disclosed by Arnold, as the wound healing factors would be able to pass through the molecular filtration membrane into the absorbent layer and away from the wound site.

As the cited references do not obviate claim 1, neither does it anticipate dependent claims 2 and 5-15. In view of the foregoing, a *prima facie* case has not been made. The Final Action has provided no reasoning to combine and/or modify Arnold et al. in the manner alleged, and even if the combinations were made, the result would not be a wound treatment device as currently claimed. Thus, Applicants respectfully request that the rejections of claims 1-2 and 5- 15 under 35 U.S.C. § 103(a) be withdrawn.

For the foregoing reasons, claims 1-2 and 5-15 are considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

Respectfully submitted,

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